SEP 2 9 2011

510(k) SUMMARY

SUBMITTER:

Sorin Group Italia
86, Via Statale 12 Nord
41037 Mirandola (MO) Italy

CONTACT PERSON:

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DATE PREPARED: August 31, 2011

DEVICE TRADE NAME: D731 MICRO 27 Ph.I.S.I.O. Arterial Filter, Sorin D731 MICRO 27 Arterial Filter with 27 micron screen with phosphorylcholine coating

D733 MICRO 40 Ph.I.S.I.O. Arterial Filter, Sorin D733 MICRO 40 Arterial Filter with 40 micron screen with phosphorylcholine coating

COMMON NAME: Arterial Filter

CLASSIFICATION NAME: Cardiopulmonary Bypass Arterial Line Blood Filter

UNMODIFIED DEVICE: D731 MICRO 27 Ph.I.S.I.O. Pediatric Arterial Filter, Dideco D731 MICRO 27 Pediatric Arterial Filter with 27 micron screen with phosphorylcholine coating

D733 MICRO 40 Ph.I.S.I.O. Pediatric Arterial Filter, Dideco D733 MICRO 40 Pediatric Arterial Filter with 40 micron screen with phosphorylcholine coating (#K051232)

PREDICATE DEVICE: Sorin AF 620 Ph.I.S.I.O. Arterial Filter

Sorin AF 640 Ph.I.S.I.O. Arterial Filter (#K093986)

DEVICE DESCRIPTION:

The D731/D733 MICRO Ph.I.S.I.O. Arterial Filters are sterile, non-pyrogenic disposable filter for use in the arterial line of the cardiopulmonary bypass circuit with flow rate not exceeding 6.0 liters/minute. The D731/D733 MICRO Ph.I.S.I.O. are Arterial Filters with 27 and 40 micron filters screen, respectively. The devices are designed to remove potentially harmful gaseous emboli, aggregated blood constituents, and particulate debris, greater than the pore size, from the arterial line perfusate.

The D731/D733 MICRO Ph.I.S.I.O. Arterial Filters are a modified version of the currently marketed D731/D733 MICRO Ph.I.S.I.O. Pediatric Arterial Filters
The modifications consist of: an increase of the recommended maximum blood flow rate from 5 to 6 LPM, a change of the device trade name from D731/D733 MICRO Ph.I.S.I.O. Pediatric Arterial Filters to D731/D733 MICRO Ph.I.S.I.O. Arterial Filters, and a change of the filter screen pore size from 20 to 27 micron for the D731 MICRO Ph.I.S.I.O. As a consequence of these modifications, the labeling has been updated.

The modified device has unchanged intended use, materials, operating principles, manufacturing process, control mechanisms, sterilization process and fundamental scientific technology.
The manufacturing process in regards to the coating is also unchanged with respect to the unmodified device.

INDICATION FOR USE:

The D731 MICRO Ph.I.S.I.O. with 27 micron screen with phosphorylcholine coating and the D733 MICRO Ph.I.S.I.O. with 40 micron screen with phosphorylcholine coating are recommended for use in the arterial line of the extracorporeal circuit during any procedure that requires cardiopulmonary bypass. The filters are used to trap and remove gaseous emboli as well as particulate debris that may be introduced through the arterial line. The device should not be used longer than 6 hours. Contact with blood for longer periods is not advised.

TECHNOLOGICAL CHARACTERISTICS:

The D731/D733 MICRO Ph.I.S.I.O. Arterial filters have the same design features, manufacturing process, control mechanisms, and operating principles when compared to the unmodified device. The D731/D733 MICRO Ph.I.S.I.O. Arterial filters utilize the same materials, filtering media and the same main blood flow path as the unmodified devices.

Except for the increase of the maximum blood flow rate from 5 LPM to 6 LPM and the change of the filter screen pore size of the D731 MICRO Ph.I.S.I.O. (modified from 20 to 27 micron), the modified D731/D733 MICRO Ph.I.S.I.O. Arterial filters are identical to the current marketed D731/D733 MICRO Ph.I.S.I.O. Pediatric Arterial filters.

No change to the intended use has been made as a result of these modifications. There are no differences in packaging type and material between the D731/D733 MICRO Ph.I.S.I.O. Arterial filters and the unmodified devices, D731/D733 MICRO Ph.I.S.I.O. Pediatric Arterial filters

Compared to the predicate device AF 620/640 Ph.I.S.I.O Arterial Filters, the modified D731/D733 MICRO Ph.I.S.I.O. Arterial filters have the same operating principles, control mechanisms, sterilization process, and fundamental scientific technology of the predicate device.

The AF 620/640 Ph.I.S.I.O Arterial Filters predicate device, have also the same recommended maximum blood flow rate of 6 LPM of the modified D731/D733 MICRO Ph.I.S.I.O Arterial filters as well as the same intended use.

The D731/D733 MICRO Ph.I.S.I.O. Arterial filters are ethylene oxide sterilized and have a non-pyrogenic fluid path. They are for single use only.

NON CLINICAL TEST RESULTS:

Applicable tests were carried out in accordance with the requirements of ISO 10993-1 and the FDA May 1st, 1995 Memorandum on the use of the ISO 10993 standard for biocompatibility testing of raw materials.

The D731/D733 MICRO Ph.I.S.I.O. Arterial Filters have exactly the same materials of the unmodified device, D731/D733 MICRO Ph.I.S.I.O. Pediatric Arterial Filters (#K051232). The same formulation of Ph.I.S.I.O. material has been also used to coat all blood contact surfaces.

As no new materials are used with respect to the unmodified device, this 510(k) cross references biocompatibility data for the D731/D733 MICRO Ph.I.S.I.O. Pediatric Arterial Filters (#K051232).

As no packaging changes have been introduced, this 510(k) cross references packaging data previously submitted for the unmodified device (#K051232).

IN VITRO TEST RESULTS:

In vitro testing was carried out in accordance with the relevant requirements of "Guidance for Cardiopulmonary Bypass Arterial Line Blood Filter 510(k) Submission" Final Guidance for Industry, dated November 29, 2000.

Testing supplied in the 510(k) premarket notification for the D731/D733 MICRO Ph.I.S.I.O. Arterial Filters includes performance testing that demonstrates compliance with performance specifications.

The tests were carried out on sterilized devices were aged (3 +1 years, worst case) comparing the D731/D733 MICRO Ph.I.S.I.O. modified Arterial Filters vs. the predicate device, AF 620/640 Ph.I.S.I.O. Arterial Filters operated at same max blood flow rate (6 LPM). The results of these tests met established specifications.

CONCLUSIONS:

The D731/D733 MICRO Ph.I.S.I.O. modified Arterial Filters are substantially equivalent to the predicate device in terms of functionality.

Additional testing has also demonstrated the effectiveness of production techniques to assure that the device is sterile and non-pyrogenic.
In conclusion, test results of this study suggest the D731/D733 MICRO Ph.I.S.I.O. Arterial Filters are equivalent to the AF 620/640 Ph.I.S.I.O. Arterial Filters with respect to device function.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 29 2011

Sorin Group Italia s.r.l.
c/o Mr. Barry Sall
Principal Consultant
Parexel International Consulting
195 West Street
Waltham, MA 02451

Re: K112525
Trade/Device Name: D731 MICRO 27 Ph.I.S.I.O. and D733 MICRO 40 Ph.I.S.I.O. Arterial Filters
Regulation Number: 21 CFR 870.4260
Regulation Name: Cardiopulmonary Bypass Arterial Line Blood Filter
Regulatory Class: Class II
Product Code: DTM
Dated: August 31, 2011
Received: August 31, 2011

Dear Mr. Sall:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be

found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K112525

510(k) Number (if known): K112525

Device Name: D731 MICRO 27 Ph.I.S.I.O., Sorin D731 MICRO 27 Arterial Filter with 27 micron screen with phosphorylcholine coating and D733 MICRO 40 Ph.I.S.I.O., Sorin D733 MICRO 40 Arterial Filter with 40 micron screen with phosphorylcholine coating

Indication for Use:

The D731 MICRO 27 Ph.I.S.I.O. with 27 micron screen with phosphorylcholine coating and the D733 MICRO 40 Ph.I.S.I.O. with 40 micron screen with phosphorylcholine coating are recommended for use in the arterial line of the extracorporeal circuit during any procedure that requires cardiopulmonary bypass. The filters are used to trap and remove gaseous emboli as well as particulate debris that may be introduced through the arterial line. The device should not be used longer than 6 hours. Contact with blood for longer periods is not advised.

Prescription Use___X____
(Part 21CFR 801 Subpart D)

Over-the- Counter Use_____
AND/OR (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K112525